

REMARKS

By the foregoing amendment, claim 1 has been amended, claims 4-7 have been canceled, and claim 9 has been newly added. Applicants submit that no new matter has been added. Support for the amendment to claim 1 can be found throughout the application and more specifically, in previous claims 5, 6, and 7. Support for newly added claim 9 can be found, for example, on page 4, lines 4-7, and on page 13, beginning line 8, through page 14, line 8. Entry of the above amendment is respectfully requested.

Priority

Applicants note with appreciation that the Office Action has acknowledged the claim of priority and indicated that some certified copies of the priority documents have been received. The Action states that correction is required because an English translation of the priority document was not provided.

Applicants respectfully disagree. Applicants submit that 37 C.F.R. § 1.55 (a)(4) regulates when a translation of a foreign priority document is required. There is no requirement, and the Office is only permitted to comment on the translation of the priority document when the cited art has a date later than Applicants' priority date. Applicants note that here, the cited art has no such date.

Applicants respectfully submit that the claim of priority is proper under 35 U.S.C. § 365 and 119 (see also MPEP § 1893.03(c)) and respectfully request withdrawal of the erroneous statements relating to Applicants' priority document and claim.

Drawings

Applicants note with appreciation that the Action accepts the drawings filed on September 14, 2006.

Information Disclosure Statement

Applicants thank the Examiner for considering documents cited in the Information Disclosure Statement filed August 15, 2007 by returning initialed copies of the Form PTO-1449 submitted therein. Furthermore, Applicants note that a Supplemental Information Disclosure Statement is being filed concurrently herewith.

Claim Rejections – 35 U.S.C. § 102(b)

The Office Action raises the following claim rejections:

- (a) Claims 1-5 are rejected under 35 U.S.C. § 102(b) as allegedly being anticipated by Sugimoto et al. (U.S. Patent No. 5,759,572);
- (b) Claims 1-4 and 6 are rejected under 35 U.S.C. § 102(b) as allegedly being anticipated by Shimizu et al. (Bioorganic and Medicinal Chemistry, 2003, 11: 1191-1195), as evidenced by Wang et al. (Chin Med J, 2000, 113: 281-285)

With regard to the rejection (a), the Action asserts that Sugimoto et al. discloses an immunostimulatory composition comprising oligosaccharide (e.g., mannopentanose or mannotriose) coated liposomes and antigens (e.g., cancer immunotherapeutic drugs). With regard to rejection (b), the Action asserts that Shimizu et al. discloses an immunostimulatory composition comprising oligomannose-coated liposomes and *Leishmania* peptide antigens, which is administered intraperitoneally. The Action also asserts that Shimizu et al. discloses that the liposomes interact with antigen-presenting cells (APCs) and deliver the antigens to the APCs.

Regarding Wang et al. and Sugimoto et al., they refer to APCs, macrophages (phagocytic activity), dendritic cells, and the like.

Applicants note that the subject matter of claim 7, not rejected under 35 U.S.C. § 102, has been incorporated into claim 1. Withdrawal of the rejections is respectfully requested.

Claim Rejections – 35 U.S.C. § 103(a)

The Office Action rejects claims 1-8 under 35 U.S.C. 103(a) as allegedly being unpatentable over Sugimoto et al. in view of each Wang et al., Koenen et al. (Cancer Immunol Immunother, 1996, 42: 310-316), Hagiwara et al. (Cancer Research, 1993, 53: 687-692), and Babincova et al. (Bioelectrochemistry, 2002, 55: 17-19).

Applicants respectfully traverse these rejections. Without admitting or conceding that the presented combinations of documents are proper or create a *prima facie* case of obviousness, Applicants submit that the presently claimed invention provides unexpected results that are sufficient to overcome any argument of obviousness.

Applicants respectfully submit that in this field, attempts have been made to deliver a drug to an intraperitoneal target site. One such attempt is the implementation of liposomes in order to increase the therapeutic effect and to reduce undesired side effects. However, attempts to modify liposomes with various cancer-specific molecules for active targeting have generally not prevailed because the expression of such molecules is not universal.

For example, it is known that activated carbon can be incorporated into breast tissue macrophages, thereby allowing development of methods for targeting macrophages. When activated carbon containing an anticancer agent is administered intraperitoneally, accumulation in breast tissue occurs. However, such accumulation requires long periods of time (~ 1 week) to become effective. Thus, although, macrophages are a convenient device for delivering, their utilization has not been established because of the lack of efficient and specific targeting methods and mechanisms.

Applicants submit that in the present invention, the liposome composition is taken up by intraperitoneal macrophages within a short period (between thirty minutes and one hour), and 60% of the composition is accumulated in breast tissue within a few hours to twelve hours. This faster delivery and high efficiency is an unexpected result, which is achieved by the drug delivery composition as claimed. Applicants respectfully submit that such unexpected results are not suggested by the cited art and could not have been predicted by the art.


Applicants respectfully submit that a *prima facie* case of obviousness is not established by the cited art. Even if it is, *arguendo*, Applicants submit that the unexpected result obtained by the present invention are sufficient to overcome any *prima facie* cases

CONCLUSION

In view of the foregoing, the Examiner is respectfully requested to reconsider and withdraw the rejections of record, and allow all the pending claims.

Should there be any questions, the Examiner is invited to contact the undersigned at the below listed telephone number.

Respectfully submitted,
Naoya KOJIMA et al.


Bruce H. Bernstein
Reg. No. 29,027 42,920

June 27, 2008
GREENBLUM & BERNSTEIN, P.L.C.
1950 Roland Clarke Place
Reston, VA 20191
(703) 716-1191